PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION See Form PCT/IPEA/416	
2031301PC/nu		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/FI2004/000618	15-10-2004	17-10-2003
International Patent Classification (IPC) or national classification and IPC		
See Supplemental Box		
Applicant		
Helsingfors Institution för Bioimmunterapi Ab		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 1 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☒ Box No. VII Certain defects in the international application
   - ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17-08-2005	16-01-2005
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer Eva Johansson / MRo Telephone No. +46 8 782 25 00

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Cover sheet

INTERNATIONAL PATENT CLASSIFICATION (IPC):

A61K 33/14 (2006.01)
A61K 31/198 (2006.01)
A61K 33/24 (2006.01)
A61P 35/00 (2006.01)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/FI2004/000618

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:

- ☐ international search (Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

☐ the international application as originally filed/furnished

☒ the description:

pages 1-13 as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☒ the claims:

pages _____ as originally filed/furnished
pages* _____ as amended (together with any statement) under Article 19
pages* 14 received by this Authority on 18-11-2005
pages* _____ received by this Authority on _____

☐ the drawings:

pages _____ as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing *(specify)*: _____
- ☐ any table(s) related to the sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing *(specify)*: _____
- ☐ any table(s) related to the sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/FI2004/000618

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	10	YES
	Claims	1-9	NO
Inventive step (IS)	Claims	10	YES
	Claims	1-9	NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The invention relates to a pharmaceutical agent that consists essentially of strontium, amino acid(s), mineral element(s) and vitamins for the treatment of cancer.

The new amended claims filed the 18th of November 2005 consists of:
Claims 1-9, describing a pharmaceutical agent comprising strontium, amino acid(s), mineral element(s) and vitamins for the treatment of cancer.
Claim 10, use of a pharmaceutical agent in the manufacture of a medicament for the treatment or prophylaxis of cancer.

Reference is made to the following document:
D1: WO 00/07607 A1

Document D1 (claims 16-17) describes a composition comprising strontium and amino acids e.g. lysine, as well as mineral elements e.g. chromium in addition of a few other components e.g. vitamins for the treatment of osteoporosis.

The information about the use for a particular purpose does not change the composition, as this is not the first medical indication. The use for a particular purpose does not in this case need to influence the contents of the composition compared to the known compositions.

The additional information of vitamins does not change the technical effect of the claims. Furthermore, the composition according to document D1 also includes vitamins.

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Box V

Accordingly, the composition described in claims 1-9 is known from document D1. Thus, the invention defined in claims 1-9 is not new and consequently lacks novelty and inventive step.

The document D1 is regarded as being the closest prior art to the subject-matter of claim 10.
The use of the composition according to claim 10 differs from document D1 in that it is used in the manufacture of a medicament for treatment or prophylaxis of cancer.
The subject-matter of claim 10 is therefore novel (Article 33(2) PCT).

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

The wording in claim 10, "for the manufacture of an agent" is not clear. It should read "in the manufacture of a medicament".

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The expression "consist essentially of" in the amended claims is not used in the specification and the expression is not supported by the specification. The expression "a preferred combination" on page 4, line 15, do not have the same meaning and can therefore not be accepted.

AMENDED CLAIMS 18 NOVEMBER 2005

1. Pharmaceutical agent for the treatment or prophylaxis of cancer, **characterized** in that it consists essentially of strontium, at least one amino acid selected from the group consisting of arginine, serine, asparagine, glycine, glutamine, lysine, at least one mineral element selected from the group consisting of chromium, tin, vanadium and wolfram, and vitamins.

2. Pharmaceutical agent according to claim 1, **characterized** in that strontium is present in the form of strontium ions.

3. Pharmaceutical agent according to claim 1, **characterized** in that strontium is present in the form of strontium chloride or strontium oxide.

4. Pharmaceutical agent according to any one of claims 1–3, **characterized** in that it comprises 0.1–3 mg strontium, at least one L-amino acid selected from the group consisting of arginine, serine, asparagine, glycine, glutamine, lysine, in an amount of 2–5 g of each of the chosen amino acids, at least one mineral element selected from the group consisting of chromium, tin, vanadium and wolfram, in an amount of 1–3 mg of each of the chosen mineral elements, the amounts being calculated as daily intake.

5. Pharmaceutical agent according to any one of claims 1–4, **characterized** in that it comprises strontium, serine and vanadium.

6. Pharmaceutical agent according to any one of claims 1–4, **characterized** in that it comprises arginine and vanadium.

7. Pharmaceutical agent according to any one of claims 1–4, **characterized** in that it comprises strontium and isoleucin and at least one mineral element selected from the group consisting of chromium, tin, vanadium, selenium, and wolfram.

8. Pharmaceutical agent according to any one of claims 1–7, **characterized** in that it is in the form of a food additive or a food ingredient.

9. Pharmaceutical agent according to claim 8, **characterized** in that it is in the form of a dairy product, preferably a yoghurt.

10. Use of a pharmaceutical agent according to any one of claims 1–7 for the manufacture of an agent for treatment or prophylaxis of cancer.